

REMARKS

Reconsideration of the application and allowance of all pending claims are respectfully requested in light of the remarks below.

Applicants thank the Examiner for his courtesies during a telephone conversation with their undersigned attorney on July 2, 2003.

In the outstanding Office Action, it appears as if the Examiner considered Mr. Wu as one of the inventors of the above-referenced application. However, as discussed during the telephone conversation, Mr. Wu is not an inventor and does not work for the assignee of this application.

It also appears as if the Examiner continues to believe that Applicants are withholding information concerning the prior art, particularly the Genentech device. Under 37 CFR 1.56, each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the U.S. Patent Office. This duty of disclosure requires that all information known to that individual to be material to patentability be disclosed at the time an application is being examined. The duty of disclosure, under rule 56, does "not create any new duty" for applicants. MPEP 2001.04.

Applicants respectfully assert that they have disclosed as much information as they can remember concerning the prior art, especially the Genentech device, and, therefore, submit that they have more than satisfied their duty of candor under Rule 56. In the Office action, the Examiner continues to request information beyond that which is either "contemporaneously or presently known" by the inventors. MPEP 2001.04. For example, the Examiner requests a declaration by Mr. Wu, a non-inventor and a non-employee of assignee Integrated Biosystems, and suggests that Applicants' counsel contact Genentech's counsel for information about a competitive system, namely, measurements of the fin sizes and the diameter of the tank and distance between the wall and tip of fin of the Genentech device. However, such a request is unnecessary (e.g. contacting a competitor for information on their own product), but also beyond the duty owed to the Patent Office by an inventor or their representatives. The relative distances

between the fins and wall are disclosed in the 1992 Wisniewski and Wu article which clearly shows a drawing of the actual device.

In the Office Action, the Examiner continues to request specific prior art or a “carefully drawn sketch” of the prior art discussed on page 2 of the specification, which discloses fins attached to the wall of the container. Applicants respectfully submit that, at the time of the filing of the application and now, they did not recall a specific device, but instead disclosed their general knowledge of a prior art device. In any case, however, such a device is not material to the patentability of the present application. Certainly, the Examiner can imagine a device having fins that extend and contact the inner wall of the container and must realize that a thermal transfer bridge cannot form in a gap between a fin tip and the container inner wall because no such gap exists when the fins attach to the inner wall. A more careful reading of Mr. Wisniewski’s Second Declaration, paragraph 9, shows that the U.S. Patents Nos. 2,441,376 and 2,129,572 were offered as examples of such devices. Mr. Wisniewski does not state that he was aware of these references at the time of filing the application. Applicants respectfully submit that there is nothing better than these two patents to illustrate fins rigidly attached to the interior wall of container.

Applicants respectfully submit that biopharmaceutical materials were processed in the prior art discussed in the Background of the Invention section of the present application.

At this point, Applicants consider the requests and statements made by the Examiner during prosecution to amount to no more than accusations of inequitable conduct. Applicants respectfully submit that there is no deceptive intent in prosecuting this application. Applicants and their counsel have been more than forthcoming and open during numerous telephone conversations and responses to Office Actions. The MPEP, in section 2010, specifically states that “the Office does not investigate and reject original ... applications under 37 CFR 1.56. Likewise, the Office will not comment upon duty of disclosure issues.” Therefore, Applicants respectfully request that the Examiner either allow this application or issue a final office action so that these matters can be introduced to and resolved by the Board on appeal.

Finally, it appears that the Examiner will continue to maintain his rejection of the claims based on obviousness of the prior art on record, despite any suggestion or motivation in any reference to extend the fins or for the formation of a thermal transfer bridge. Based on the most recent telephone conversation, the Examiner maintains that it would be obvious to extend the fins in the prior art closer to the interior wall so that a thermal transfer bridge is formed. Also, it is the Examiner's contention that the prior art will also form a thermal transfer bridge over time anyway.

As stated in Mr. Wisniewski's second declaration, the fins of the Genentech vessel were small and thin and designed only to aid the freezing around the loop pipe in order to increase the relatively small surface area of the pipe. See Wisniewski Second Declaration, ¶8. Further, Applicants respectfully disagree with and traverse the Examiner's contentions, which are unsupported by any evidence, including documentary evidence. The fact that the Examiner believes a thermal transfer bridge will form in the prior art eventually based on his general knowledge of physics is not enough. "It is never appropriate to rely solely on "common knowledge" in the art without evidentiary support in the record, as the principal evidence which the rejection is based." MPEP 2144.03. In the instant case, the Examiner's assessment of basic knowledge and common sense is not based on any evidence in the record and therefore lacks substantial evidence support for the obviousness rejection. The mere skepticism of Applicants' invention is simply not enough to support the rejection of the claims.

The Examiner completely lacks any specific factual findings or concrete evidence to support his opinion and mere conclusion that the prior art will eventually form a thermal transfer bridge. Official notice without documentary evidence to support an examiner's conclusion should only be taken by the examiner where the facts asserted are well-known or are common knowledge in the art are capable of "instant and unquestionable demonstration" as being well-known. MPEP 2144.03. However, the Examiner requests that Applicants perform experimentation by cutting back the fins in its invention and taking the temperature of numerous locations over time. However, this is not Applicant's burden, but rather the Examiner's burden to support his contention that a thermal transfer bridge eventually forms in the prior art devices. The fact that the Examiner requests experimentation clearly shows that his conclusion is not

well-known or common knowledge in the art or supported by any reference capable of instant and unquestionable demonstration.

Therefore, Applicants maintains its traversal of the Examiner's reliance on his own general knowledge of physics, especially when dealing with biopharmaceutical products, and again requests that the Examiner provide specific factual findings predicated on sound technical and scientific reasoning to support his conclusion of common knowledge, including a reference or affidavit in support of such opinion or in contradiction to the declarations on record of Mr. Wisniewski and his extensive experience in this field. Applicants also respectfully traverse the Examiner's contention that an ice bridge is the same as a thermal transfer bridge.

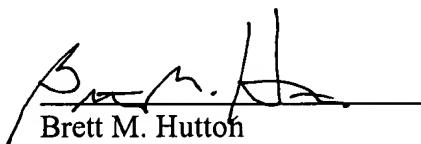
Again, Applicants thank the Examiner for his time during the telephone conversation on July 2, 2003 and respectfully request that the claims be allowed or a final rejection be issued so that these issues may be appealed to the Board.

Conclusion

For the foregoing reasons, it is respectfully submitted that the pending claims are in condition for allowance. If any issues exist, or if the Examiner has any suggestions for expediting allowance of the application, the Examiner is invited to contact the undersigned.

Respectfully submitted,

Dated: July 10, 2003



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